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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,069	11/09/2000	Joseph R. Codispoti	MCP-264	3552

7590 01/23/2004

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EXAMINER
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JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/709,069

Applicant(s)

CODISPOTI, JOSEPH R.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/23/03. 6) ☐ Other: \_\_\_\_

***Claims 1-26 and 31-36 are pending in this application.***

***Response to Amendment***

The Declaration filed on 7 November, 2003 under 37 CFR 1.131 is sufficient to overcome the Furey et al. abstract. It is noted that this rejection does not appear in the office action dated 16 July, 2003, however, this response is made in the interest of clarity.

***Response to Arguments***

Applicant's arguments filed 23 October 2003 have been fully considered but they are not persuasive. The rejection made in the paper mailed 16 July 2003 over Martindale The Complete Drug Reference 1999 under 35 U.S.C. §103(a) is maintained and is hereby repeated.

Applicant asserts that Martindale's fails to disclose or suggest the use of ibuprofen as opposed to a multitude of other NSAIDS. Since it is well known by one of ordinary skill in the art that ibuprofen is an NSAID, and it is readily accessible to a patient having a migraine since it is available over-the-counter, it would have been obvious to employ ibuprofen to treat a migraine. Applicant asserts that Martindale's fails to disclose or suggest the use of ibuprofen alone as the sole anti-migraine agent. The reference clearly recites that treatment with NSAID's are effective if taken at the earliest signs of an attack, thus, disclosing treatment with the NSAID ibuprofen as the sole anti-migraine agent. Applicant further asserts that the reference fails to teach specifically

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mitigating or treating photophobia/phonophobia associated with a migraine. Since photophobia and phonophobia are part of the symptoms that accompanies a migraine headache, (page 443, column 2, 4<sup>th</sup> full paragraph) as the ibuprofen alleviates the migraine headache, it would alleviate the symptoms that stem from the migraine itself such as photophobia and phonophobia.

Applicant's arguments filed 23 October 2003 have been fully considered but they are not persuasive. The rejection made in the paper mailed 16 July 2003 over Diener in view of Mauskop 35 U.S.C. §103(a) is maintained and is hereby repeated.

Applicant asserts that Diener fails to disclose or suggest that specifically ibuprofen is useful for the specifically claimed symptom, i.e. mitigating or treating photophobia/phonophobia associated with a migraine. Since photophobia and phonophobia are part of the symptoms that accompanies a migraine headaches disclosed by Diener, as the ibuprofen alleviates the migraine headache, it would alleviate the symptoms that stem from the migraine itself such as photophobia and phonophobia. Applicant further alleges that Diener fails to disclose or suggest that migraines may be treated solely with an analgesic, but suggests that providing an antiemetic first. It is well known that accompanying symptoms of a migraine sometimes include nausea and vomiting. Diener suggests adding an antiemetic when nausea and vomiting preclude ingestion of said analgesic (i.e. ibuprofen). Each migraine has its own set of symptoms that accompany the migraine such as nausea, vomiting, gastrointestinal stasis, aura as well as photophobia and phonophobia. Each of these symptoms may or may not accompany the pain that is marked by said migraine.

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Applicant asserts that Mauskop neither discloses nor suggests the use of ibuprofen, isomers thereof or mixtures thereof as the sole anti-migraine agents for treatment or mitigation of photophobia or phonophobia. Further applicant alleges that Mauskop provides that the combination of a magnesium salt and the analgesic agents exert a synergistic effect for relieving pain and related migraine symptoms. Mauskop recites, "When added as a separate component, the magnesium salt is present in the magnesium-containing composition at levels ranging from 5-30 wt%, preferably 10-30 wt%. When a **single compound of a magnesium salt of the analgesic agent** is used, the amounts of such as single compound would be between about 20 and 95 wt% of the composition (column 3, lines 9-17). This would read on applicants instant claims drawn to a *inter alia* magnesium salt of ibuprofen. Applicant has asserted that there is a recitation of synergy between the magnesium salt and the analgesic for relief of pain and related migraine symptoms in column 3, lines 23-26. This was not found by the examiner. Applicant is reminded that the rejection is made over Mauskop U.S. Patent No. 5,538,959 A, not U.S. 5,914,129 where the applicant appears to be referring.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diener et al. (AG)

The claims are drawn to a method of mitigating or treating photophobia/phonophobia associated with a migraine by providing an effective amount of ibuprofen to the stomach of the patient in need of treatment.

Diener et al. teach that aspirin, **ibuprofen** and paracetamol (acetaminophen) are noted as first-choice analgesics for mild to moderate migraine attacks (page 813, column 2, lines 3-5). Diener et al (U) further teach that migraine is a paroxysmal disorder with attacks of headache, nausea, vomiting, photophobia, phonophobia and malaise (see abstract).

It differs from the instant claims in that it does not explicitly teach targeting photo and phonophobia and it does not teach administering the dose to the stomach of the patient.

Since photophobia and phonophobia are part of the symptoms that accompanies a migraine headache, as the ibuprofen alleviates the migraine headache, it would alleviate the symptoms that stem from the migraine itself such as photophobia and phonophobia.

Since the only method of administration of ibuprofen is perorally, then the dose would have no alternative than to be delivered to the stomach of the patient.

It would have been made obvious to one of ordinary skill in art at the time it was made to treat photophobia/phonophobia associated with a migraine by administering ibuprofen to the stomach of a patient motivated by the teaching of Diener et al. who teaches that ibuprofen is useful for treating migraines and that migraine headaches are accompanied by symptoms such as photophobia and phonophobia. It would have been made obvious to one of ordinary skill in art at the time it was made to administer the dose of ibuprofen to the stomach of a patient suffering from a migraine since it is well known in the art that perorally is the only approved method of administration of ibuprofen.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

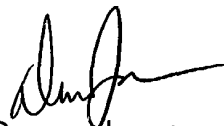
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3230.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Donna Jagoe  
Patent Examiner  
Art Unit 1614

Frederick Krass  
Primary Examiner  
Art Unit 1614

